K021757

JUL 2 9 2002

510(k) SUMMARY

Safety and Effectiveness

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

CRPex-BR C-Reactive Protein LIT Assay

Submitter

Name,	Good Biotech Corp.
Address,	38 34th Rd. Taichung Industrial Park Taichung City 407 Taiwan R.O.C.
Telephone number,	+886-4-23596873
Contact person,	Victor Chiou
Preparation date	May 24, 2002

Device

Trade name,	CRPex-BR C-reactive protein LIT assay CRPex-BR CRP calibrator set
Common name,	CRP immunological diagnostic assay
Classification name	C-reactive protein immunological test system (21CFR 866.5270)

Predicate Device

Trade name,	K-ASSAY CRP (1) K-ASSAY multi-calibrator.C
510(k) number	K992311

Description

CRPex-BR C-reactive protein LIT Kit is the ready-to-use reagent suitable for quantification of C-reactive protein by latex particle enhanced immunoturbidimetry (LIT). Duck anti-CRP IgY (ΔFc) is

coupled to polystyrene microparticles, which greatly increased the analytical sensitivity.

Intended Use

Good Biotech Corp. CRPex-BR C-reactive protein LIT kit is intended to be used for quantitative determination of C-reactive protein in serum. The measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.
For *in vitro* diagnostic use.

Substantial Equivalence

CRPex-BR C-reactive protein LIT kit is compared with Kamiya Biomedical Company's K-ASSAY CRP (1) to demonstrate the substantial equivalence.

Item\Device	CRPex-BR CRP LIT Kit	K-ASSAY CRP (1)
Intended Use	Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.	Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.
Methodology	Latex particle enhanced immunoturbidimetry	Latex particle enhanced immunoturbidimetry
Test Objective	C-reactive protein	C-reactive protein
Test Principle	Latex microparticle agglutination based on antigen-antibody reaction	Latex microparticle agglutination based on antigen-antibody reaction
Type of Test	Quantitative	Quantitative
Product Type	Reagent 1 (R 1): Reactive buffer solution Reagent 2 (R 2): Latex suspension	Reagent 1 (R 1): Reactive buffer solution Reagent 2 (R 2): Latex suspension

Antibody 【Source】	Duck anti-CRP IgY(ΔFc) 【Egg Yolk】	Rabbit anti-CRP antibodies 【Serum】
Sterility	N.A.	N.A.
Specimen	Human serum	Human serum
Operating Requirement	For professional use only	For professional use only
Calibration Mode	Spline	Spline
Calibrator	CRPex-BR Calibrator Set	K-ASSAY CRP Multi-Calibrator Set C (standard protocol); K-ASSAY CRP Multi-Calibrator Set A (high sensitivity protocol)
Sample Volume	3 µl/test	3 (15) µl/test
Reagent Volume	R1 : 150 µl/test R2 : 150 µl/test	R1 : 150 µl/test R2 : 150 µl/test
Wavelength Selection	Main-wavelength:570 nm Sub-wavelength: 800 nm	Main-wavelength:570 nm Sub-wavelength: 800 nm
Assay Code 【Hitachi 717 (7150)】	2 point: (27)-(40)	2 point: (28)-(42)
Assay Range	1-300 mg/L	1-300 mg/L (standard protocol) 0.1-20 mg/L (high sensitivity protocol)
Calibration Curve	Nearly linear	Nearly Curved
Interference	Bilirubin C: up to 60 mg/dl Bilirubin F: up to 60 mg/dl Hemolysis: up to 500-mg/dl hemoglobin Lipemia: up to 10 g/L Liposyn® (fat emulsion)	Bilirubin C: up to 60 mg/dl Bilirubin F: up to 60 mg/dl Hemoglobin: up to 500 mg/dl Lipid: up to 1500 mg/dl triglyceride

Correlation

$y = 0.976\,x + 1.179$ mg/L

x = K-ASSAY CRP (1)

y = CRPex-BR C-reactive protein LIT kit

$R^2 = 0.998$

N = 94

Conclusion

Good Biotech Corp.'s CRPex-BR C-reactive protein LIT kit is substantially equivalent to the predicate device K-ASSAY CRP (1).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor Choiu
President
Good Biotech Corp.
38 34th Raod – Taichung Industrial Park
407 Taichung City, Taiwan
Taiwan R.O.C.

JUL 29 2002

Re: k021757
Trade/Device Name: CRPex-BR C-reactive protein LIT assay
CRPex-BR CRP calibrator set
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: May 24, 2002
Received: May 29, 2002

Dear Mr. Choiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K021757

Device Name: CRPex-BR C-reactive protein LIT assay
CRPex-BR CRP calibrator set

Indications For Use:

Good Biotech Corp. CRPex-BR C-reactive protein LIT assay is intended to be used for the quantitative determination of C-reactive protein in serum by latex particle enhanced immunoturbidimetry. The measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

Good Biotech Corp. CRPex-BR CRP calibrator set is intended to be used with CRPex-BR C-reactive protein LIT assay for the quantitative determination of C-reactive protein in serum samples.

For In Vitro Diagnostic Use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for G. Altaire

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021757

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)